Ansell Perry

October 5, 1999

'1648 '99 OCT -6 :20:12

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0313
Surgeon's and Patient Examination gloves; Reclassification

Dear Sir or Madam:

Ansell Healthcare Products Inc. ("Ansell"), a major manufacturer of medical gloves for the United States and international markets, hereby requests an extension for an additional 90 days of the period in which comments may be submitted on the above referenced proposed rule published in the Federal Register of July 30, 1999 (64 Fed. Reg. 41710).

One of the most important issues addressed in this proposal is the recommended powder limit for powdered gloves. The American Society for Testing and Materials (ASTM) is presently in the process of conducting ballots for revisions of its standards to include a recommended maximum powder limit in its standards for latex surgeon's gloves, latex patient examination gloves, polyvinyl medical gloves and nitrile patient examination gloves. This process is estimated by ASTM to be completed within the requested additional 90 days, The requested extension thus would allow FDA to consider, and Ansell and others to comment on, the recommendations of this important standard setting organization on this important issue.

Respectfully submitted,

ANSELL PERRY

James R. Chatterton
Vice President Regulatory

JRC/km

98N-0313

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FROM: Kathy Mack (330)833-2811
Ansell Perry, Inc.
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